K052002

AUG 2 2 2005

510(k) Summary

Introduction

According to the requirements of 21 CFR 807.92, the following information provides sufficient detail to understand the basis for a determination of substantial equivalence

Submitter's name, address, and contact

Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250
317-521-3831

Contact Person: Corina Harper

Date Prepared: July 22, 2005

Device name

Proprietary name: Iron Standard

Common name: Calibrator

Classification name: Calibrator, Secondary, Class II

Predicate device

The Iron Standard is substantially equivalent to the currently marketed Elecsys® C-Peptide Calset (K033873).

Device description

The Iron Standard is a single-level product consisting of a gravimetrically prepared aqueous solution of Ferrous Ammonium Sulfate Hexahydrate.

Intended use

Iron Standard is for use in the calibration of quantitative Unsaturated Iron Binding Capacity (UIBC) assays on Roche clinical chemistry analyzers.

Continued on next page

Substantial equivalence: Similarities

The Iron Standard is substantially equivalent to the currently marketed Elecsys® C-Peptide Calset (K033873). The below tables compare Iron Standard with the predicate device, Elecsys® C-Peptide Calset.

Characteristic	Iron Standard	Predicate Device Elecsys® C-Peptide Calset (K033873)
Intended Use	For use in the calibration of quantitative Unsaturated Iron Binding Capacity (UIBC) assays on Roche clinical chemistry analyzers.	For calibrating the quantitative Elecsys® C-Peptide assay on the Elecsys® immunoassay systems.
Levels	One	Two

Continued on next page

Substantial equivalence: Differences

The below tables compare Iron Standard with the predicate device, Elecsys® C-Peptide Calset.

Characteristic	Iron Standard	Predicate Device Elecsys® C-Peptide Calset (K033873)
Format	Aqueous solution	Lyophilized
Handling	Ready to use	Add exactly 1.0 ml distilled water and allow to stand closed for 15 minutes to reconstitute. Mix carefully, avoiding the formation of foam.
Stability	Unopened: • Store at 15-25°C until expiration date After opening: • 15-25°C: until expiration date	Unopened: • Store at 2-8°C until expiration date Reconstituted: • -20°C: 1 month (freeze only once) • On the analyzers at 20-25°C: use only once
Matrix	Gravimetrically prepared aqueous solution of Ferrous Ammonium Sulfate Hexahydrate.	Equine serum with added synthetic human C-Peptide.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

AUG 2 2 2005

Ms. Corina Harper, RAC
Regulatory Affairs Consultant
Roche Diagnostics
9115 Hague Road
Indianapolis, IN 46250

Re: k052002
Trade/Device Name: Iron Standard
Regulation Number: 21 CFR 862.1150
Regulation Name: Calibrator
Regulatory Class: Class II
Product Code: JIT
Dated: July 22, 2005
Received: July 25, 2005

Dear Ms. Harper:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in Title 21, Code of Federal Regulations (CFR), Parts 800 to 895. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Parts 801 and 809); and good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820).

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific information about the application of labeling requirements to your device, or questions on the promotion and advertising of your device, please contact the Office of In Vitro Diagnostic Device Evaluation and Safety at (240) 276-0484. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Carol C. Benson

Carol C. Benson, M.A.
Acting Director
Division of Chemistry and Toxicology
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K052002

Device Name:

Iron Standard

Indications For Use:

Iron Standard is for use in the calibration of quantitative Unsaturated Iron Binding Capacity (UIBC) assays on Roche clinical chemistry analyzers.

Prescription Use **XXXX** AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostic Devices (OIVD)

Division Sign-Off

Office of In Vitro Diagnostic Device
Evaluation and Safety

510(k) K052002